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BECTON, DICKINSON AND COMPANY

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF CALIFORNIA

17 GEN-PROBE INCORPORATED

) Case No. 09cv2319 BEN (NJS)

18 Plaintiff.

) ANSWER AND COUNTERCLAIM OF
) DEFENDANT BECTON, DICKINSON
) AND COMPANY

20 | BECTON, DICKINSON AND COMPANY

3

21 || Defendant.

JURY TRIAL DEMANDED

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Defendant Becton, Dickinson and Company (“BD”) hereby responds to the numbered paragraphs of the Complaint of plaintiff Gen-Probe Incorporated (“Gen-Probe”) as follows:

1. Paragraph 1 is an introductory statement that does not require any response. To the extent a response is required, BD denies the allegations set forth in paragraph 1 except that BD admits that Gen-Probe markets equipment and nucleic acid tests for the detection of Chlamydia trachomatis and Neisseria gonorrhoeae.

THE PARTIES

2. BD lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations set forth in paragraph 2, and on that basis denies the allegations.

10 || 3. BD admits the allegations of paragraph 3.

11 4. BD admits that the Gen-Probe TIGRIS System is being used in some clinical
12 laboratories for diagnosis of diseases including Chlamydia trachomatis and Neisseria
13 gonorrhoeae. BD lacks knowledge or information sufficient to form a belief as to the truth or
14 falsity of the remaining allegations set forth in paragraph 4, and on that basis denies the
15 allegations.

JURISDICTION AND VENUE

17 || 5. BD admits the allegations of paragraph 5.

18 6. BD admits that it has a regular place of business and that it transacts business
19 within this judicial district. BD denies all remaining allegations of paragraph 6.

BACKGROUND

21 || 7. BD admits the allegations of paragraph 7.

22 || 8. BD admits the allegations of paragraph 8.

23 || 9. BD admits the allegations of paragraph 9.

24 || 10. BD admits the allegations of paragraph 10.

25 11. BD admits the allegations of paragraph 11.

26 || 12. BD admits the allegations of paragraph 12.

27 || 13. BD admits the allegations of paragraph 13.

28 || 14. BD admits the allegations of paragraph 14.

1 15. BD lacks knowledge or information sufficient to form a belief as to the truth or
2 falsity of the allegations set forth in paragraph 15, and on that basis denies the allegations.

COUNT ONE (THE '256 PATENT)

4 16. BD repeats and incorporates herein its responses to paragraphs 1 through 15.

5 17. BD denies that it has practiced or infringed, or is practicing or infringing, directly
6 or indirectly, any claim of United States Patent No. 7,560,256 (“the ’256 patent”). BD admits
7 that it has actual knowledge of the ’256 patent. BD admits that it manufactures and distributes a
8 product called the “BD Viper™ System with XTR™ Technology” and that it provides written
9 information to customers concerning the use of that product. BD denies all remaining
10 allegations of paragraph 17.

11 || 18. BD denies the allegations of paragraph 18.

12 || 19. BD denies the allegations of paragraph 19.

COUNT TWO (THE '255 PATENT)

14 20. BD repeats and incorporates herein its responses to paragraphs 1 through 15.

15 21. BD denies that it has practiced or infringed, or is practicing or infringing, directly
16 or indirectly, any claim of United States Patent No. 7,560,255 (“the ’255 patent”). BD admits
17 that it has actual knowledge of the ’255 patent. BD admits that it manufactures and distributes a
18 product called the “BD Viper™ System with XTR™ Technology” and that it provides written
19 information to customers concerning the use of that product. BD denies all remaining
20 allegations of paragraph 21.

21 || 22. BD denies the allegations of paragraph 22.

22 || 23. BD denies the allegations of paragraph 23.

COUNT THREE (THE '652 PATENT)

24. BD repeats and incorporates herein its responses to paragraphs 1 through 15.

25. BD denies that it has practiced or infringed, or is practicing or infringing, directly
26 or indirectly, any claim of United States Patent No. 7,524,652 (“the ’652 patent”). BD admits
27 that it has actual knowledge of the ’652 patent. BD admits that it manufactures and distributes a
28 product called the “BD Viper™ System with XTR™ Technology” and that it provides written

1 information to customers concerning the use of that product. BD denies all remaining
2 allegations of paragraph 25.

3 26. BD denies the allegations of paragraph 26.

4 27. BD denies the allegations of paragraph 27.

5 **COUNT FOUR (THE '143 PATENT)**

6 28. BD repeats and incorporates herein its responses to paragraphs 1 through 15.

7 29. BD denies that it has practiced or infringed, or is practicing or infringing, directly
8 or indirectly, any claim of United States Patent No. 7,482,143 ("the '143 patent"). BD admits
9 that it has actual knowledge of the '143 patent. BD admits that it manufactures and distributes a
10 product called the "BD Viper™ System with XTR™ Technology" and that it provides written
11 information to customers concerning the use of that product. BD denies all remaining
12 allegations of paragraph 29.

13 30. BD denies the allegations of paragraph 30.

14 31. BD denies the allegations of paragraph 31.

15 **COUNT FIVE (THE '892 PATENT)**

16 32. BD repeats and incorporates herein its responses to paragraphs 1 through 15.

17 33. BD denies that it has practiced or infringed, or is practicing or infringing, directly
18 or indirectly, any claim of United States Patent No. 7,118,892 ("the '892 patent"). BD admits
19 that it has actual knowledge of the '892 patent. BD admits that it manufactures and distributes a
20 product called the "BD Viper™ System with XTR™ Technology" and that it provides written
21 information to customers concerning the use of that product. BD denies all remaining
22 allegations of paragraph 33.

23 34. BD denies the allegations of paragraph 34.

24 35. BD denies the allegations of paragraph 35.

25 **COUNT SIX (THE '200 PATENT)**

26 36. BD repeats and incorporates herein its responses to paragraphs 1 through 15.

27 37. BD denies that it has practiced or infringed, or is practicing or infringing, directly
28 or indirectly, any claim of United States Patent No. 5,612,200 ("the '200 patent"). BD admits

1 that it has actual knowledge of the '200 patent. BD admits that it manufactures and distributes
2 products called the "BD Viper System™" and "BD Viper™ System with XTR™ Technology"
3 and that it provides written information to customers concerning the use of those products. BD
4 denies all remaining allegations of paragraph 37.

5 38. BD denies the allegations of paragraph 38.

6 39. BD denies the allegations of paragraph 39.

7 **COUNT SEVEN (THE '308 PATENT)**

8 40. BD repeats and incorporates herein its responses to paragraphs 1 through 15.

9 41. BD denies that it has practiced or infringed, or is practicing or infringing, directly
10 or indirectly, any claim of United States Patent No. 7,294,308 ("the '308 patent"). BD admits
11 that it has actual knowledge of the '308 patent. BD admits that it manufactures, distributes and
12 sells products called the "Female Endocervical Specimen Collection Kit for BD ProbeTec™
13 CT/GC Q^x Amplified DNA Assays" and "Male Urethral Specimen Collection Kit for BD
14 ProbeTec™ CT/GC Q^x Amplified DNA Assays" and that it provides written information to
15 customers concerning the use of those products. BD denies all remaining allegations of
16 paragraph 41.

17 42. BD denies the allegations of paragraph 42.

18 43. BD denies the allegations of paragraph 43.

19 **COUNT EIGHT (THE '612 PATENT)**

20 44. BD repeats and incorporates herein its responses to paragraphs 1 through 15.

21 45. BD denies that it has practiced or infringed, or is practicing or infringing, directly
22 or indirectly, any claim of United States Patent No. 6,893,612 ("the '612 patent"). BD admits
23 that it has actual knowledge of the '612 patent. BD admits that it manufactures, distributes and
24 sells products called the "Female Endocervical Specimen Collection Kit for BD ProbeTec™
25 CT/GC Q^x Amplified DNA Assays" and "Male Urethral Specimen Collection Kit for BD
26 ProbeTec™ CT/GC Q^x Amplified DNA Assays" and that it provides written information to
27 customers concerning the use of those products. BD denies all remaining allegations of
28 paragraph 45.

1 46. BD denies the allegations of paragraph 46.

2 47. BD denies the allegations of paragraph 47.

AFFIRMATIVE DEFENSES

First Defense

5 The claims of United States Patent No. 7,560,256 (“the ’256 patent”) are invalid for
6 failure to comply with the conditions and requirements for patentability set forth in one or more
7 of 35 U.S.C. §§ 101, 102, 103, or 112 and/or under the doctrine of obviousness-type double
8 patenting.

Second Defense

10 The claims of United States Patent No. 7,560,255 (“the ’255 patent”) are invalid for
11 failure to comply with the conditions and requirements for patentability set forth in one or more
12 of 35 U.S.C. §§ 101, 102, 103, or 112 and/or under the doctrine of obviousness-type double
13 patenting.

Third Defense

15 The claims of United States Patent No. 7,524,652 (“the ’652 patent”) are invalid for
16 failure to comply with the conditions and requirements for patentability set forth in one or more
17 of 35 U.S.C. §§ 101, 102, 103, or 112 and/or under the doctrine of obviousness-type double
18 patenting.

Fourth Defense

20 The claims of United States Patent No. 7,482,143 (“the ’143 patent”) are invalid for
21 failure to comply with the conditions and requirements for patentability set forth in one or more
22 of 35 U.S.C. §§ 101, 102, 103, or 112 and/or under the doctrine of obviousness-type double
23 patenting.

Fifth Defense

25 The claims of United States Patent No. 7,118,892 (“the ’892 patent”) are invalid for
26 failure to comply with the conditions and requirements for patentability set forth in one or more
27 of 35 U.S.C. §§ 101, 102, 103, or 112 and/or under the doctrine of obviousness-type double
28 patenting.

1 Sixth Defense

2 The claims of United States Patent No. 5,612,200 (“the ’200 patent”) are invalid for
3 failure to comply with the conditions and requirements for patentability set forth in one or more
4 of 35 U.S.C. §§ 101, 102, 103, or 112.

5 Seventh Defense

6 The claims of United States Patent No. 7,294,308 (“the ’308 patent”) are invalid for
7 failure to comply with the conditions and requirements for patentability set forth in one or more
8 of 35 U.S.C. §§ 101, 102, 103, or 112 and/or under the doctrine of obviousness-type double
9 patenting.

10 Eighth Defense

11 The claims of United States Patent No. 6,893,612 (“the ’612 patent”) are invalid for
12 failure to comply with the conditions and requirements for patentability set forth in one or more
13 of 35 U.S.C. §§ 101, 102, 103, or 112 and/or under the doctrine of obviousness-type double
14 patenting.

15 Ninth Defense

16 Gen-Probe is not entitled to relief against BD because BD is not practicing or infringing,
17 and has not practiced or infringed, either directly or indirectly, any valid claim of the ’256 patent,
18 ’255 patent, ’652 patent, ’143 patent, ’892 patent, ’200 patent, ’308 patent, or ’612 patent.

19 Tenth Defense

20 Some or all of Gen-Probe’s claims for relief are barred by the doctrines of waiver, laches,
21 and/or estoppel, including but not limited to estoppel based on representations to the United
22 States Patent and Trademark Office during prosecution of the ’256 patent, ’255 patent, ’652
23 patent, ’143 patent, ’892 patent, ’200 patent, ’308 patent, and/or ’612 patent.

24 Eleventh Defense

25 Some or all of the accused acts are exempt from liability under 35 U.S.C. § 271(e)(1).

26 Twelfth Defense

27 On information and belief, Gen-Probe’s claims for damages are limited by the provisions
28 of 35 U.S.C. § 287.

Thirteenth Defense

Some or all of Gen-Probe's claims for relief are barred by the doctrine of unclean hands.

COUNTERCLAIMS OF BECTON, DICKINSON AND COMPANY

Becton, Dickinson and Company ("BD"), for its Counterclaim against Gen-Probe Incorporated ("Gen-Probe"), alleges as follows:

PARTIES, JURISDICTION AND VENUE

1. BD, the Counterclaimant in this Counterclaim, is a New Jersey corporation having a principal place of business at 1 Becton Drive, Franklin Lakes, New Jersey 07417.

2. Gen-Probe, the Counterdefendant in this Counterclaim, has alleged that it is a Delaware corporation having a principal place of business at 10210 Genetic Center Drive, San Diego, California 92121.

3. There is an actual dispute and controversy between the parties as to whether the claims of the patents asserted in Gen-Probe's Complaint are valid.

4. This Court has jurisdiction over this Counterclaim pursuant to 28 U.S.C. §§ 1331, 1338(a), 1376, and 2201. Venue is proper under 28 U.S.C. §§ 1391 and 1400(b), and by Counterdefendant's choice of forum.

COUNT ONE

Declaratory Judgment of Invalidity ('256 patent)

5. The claims of United States Patent No. 7,560,256 ("the '256 patent") are invalid for failure to comply with the conditions and requirements for patentability set forth in one or more of 35 U.S.C. §§ 101, 102, 103, or 112 and/or under the doctrine of obviousness-type double patenting.

COUNT TWO

Declaratory Judgment of Invalidity ('255 patent)

6. The claims of United States Patent No. 7,560,255 ("the '255 patent") are invalid for failure to comply with the conditions and requirements for patentability set forth in one or more of 35 U.S.C. §§ 101, 102, 103, or 112 and/or under the doctrine of obviousness-type double patenting.

1 **COUNT THREE**

2 Declaratory Judgment of Invalidity ('652 patent)

3 7. The claims of United States Patent No. 7,524,652 ("the '652 patent") are invalid
4 for failure to comply with the conditions and requirements for patentability set forth in one or
5 more of 35 U.S.C. §§ 101, 102, 103, or 112 and/or under the doctrine of obviousness-type double
6 patenting.

7 **COUNT FOUR**

8 Declaratory Judgment of Invalidity ('143 patent)

9 8. The claims of United States Patent No. 7,482,143 ("the '143 patent") are invalid
10 for failure to comply with the conditions and requirements for patentability set forth in one or
11 more of 35 U.S.C. §§ 101, 102, 103, or 112 and/or under the doctrine of obviousness-type double
12 patenting.

13 **COUNT FIVE**

14 Declaratory Judgment of Invalidity ('892 patent)

15 9. The claims of United States Patent No. 7,118,892 ("the '892 patent") are invalid
16 for failure to comply with the conditions and requirements for patentability set forth in one or
17 more of 35 U.S.C. §§ 101, 102, 103, or 112 and/or under the doctrine of obviousness-type double
18 patenting.

19 **COUNT SIX**

20 Declaratory Judgment of Invalidity ('200 patent)

21 10. The claims of United States Patent No. 5,612,200 ("the '200 patent") are invalid
22 for failure to comply with the conditions and requirements for patentability set forth in one or
23 more of 35 U.S.C. §§ 101, 102, 103 or 112.

24 **COUNT SEVEN**

25 Declaratory Judgment of Invalidity ('308 patent)

26 11. The claims of United States Patent No. 7,294,308 ("the '308 patent") are invalid
27 for failure to comply with the conditions and requirements for patentability set forth in one or
28

1 more of 35 U.S.C. §§ 101, 102, 103, or 112 and/or under the doctrine of obviousness-type double
2 patenting.

3 **COUNT EIGHT**

4 **Declaratory Judgment of Invalidity ('612 patent)**

5 12. The claims of United States Patent No. 6,893,612 ("the '612 patent") are invalid
6 for failure to comply with the conditions and requirements for patentability set forth in one or
7 more of 35 U.S.C. §§ 101, 102, 103, or 112 and/or under the doctrine of obviousness-type double
8 patenting.

9 **JURY DEMAND**

10 Pursuant to Fed R. Civ. P. 38(b), BD requests a trial by jury with respect to Gen-
11 Probe's claims and BD's counterclaims.

12 **WHEREFORE**, BD respectfully requests the following relief:

13 A. That the Court enter judgment in favor of BD on all counts of Gen-Probe's
14 Complaint;

15 B. That Gen-Probe's Complaint be dismissed with prejudice;

16 C. That the Court enter judgment in favor of BD on all counts of BD's Counterclaim;

17 D. That the claims of United States Patent No. 7,560,256 be declared invalid;

18 E. That the claims of United States Patent No. 7,560,255 be declared invalid;

19 F. That the claims of United States Patent No. 7,524,652 be declared invalid;

20 G. That the claims of United States Patent No. 7,482,143 be declared invalid;

21 H. That the claims of United States Patent No. 7,118,892 be declared invalid;

22 I. That the claims of United States Patent No. 5,612,200 be declared invalid;

23 J. That the claims of United States Patent No. 7,294,308 be declared invalid;

24 K. That the claims of United States Patent No. 6,893,612 be declared invalid;

25 L. That BD be awarded all its costs and disbursements in this action, together with
26 its attorneys' fees incurred herein; and

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28 ///

1 M. That this Court order such other and further relief as this Court deems just and
2 proper.

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Respectfully submitted,

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KNOBBE, MARTENS, OLSON & BEAR, LLP

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Dated: December 9, 2009

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By: s/Erik T. Anderson

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Boris Zelkind
Erik T. Anderson

10

and

11

FOLEY HOAG LLP

12

Donald R. Ware (*pro hac vice* pending)
Barbara A. Fiacco (*pro hac vice* pending)
Brian C. Carroll (*pro hac vice* pending)

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Attorneys for Defendant
BECTON, DICKINSON AND COMPANY

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CERTIFICATE OF SERVICE

2 I hereby certify that on December 9, 2009 I caused the ANSWER AND
3 COUNTERCLAIM OF DEFENDANT BECTON, DICKINSON AND COMPANY to be
4 electronically filed with the Clerk of the Court using the CM/ECF system which will send
5 electronic notification of such filing to the following person(s):

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I certify and declare under penalty of perjury under the laws of the State of California that
I am employed in the office of a member of the bar of this Court at whose direction the service
was made, and that the forgoing is true and correct.

Executed on December 9, 2009, at San Diego, California.

Megan Ptacin

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